K123113

pg 1/2

510(K) SUMMARY

DEC 1 1 2012

Name of 510(k) sponsor:	GlycoBioSciences, Inc.
Address:	7 Timber Court Georgetown, Ontario L7G 4S4 Canada
Contact information:	Kevin Drizen President GlycoBioSciences, Inc. 7 Timber Court Georgetown, Ontario L7G 4S4 Canada Phone: 905-854-0631 Fax: 905-702-1709
Date summary prepared:	September 21, 2012
Proprietary name of device:	L.A.M. IPM Wound Gel
Generic/classification name:	Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic
Product code (classification):	Product Code FRO; Unclassified

Legally Marketed Predicate Devices: Bionect® Hydrogel (K984413); February 10, 1999
L.A.M IPM Wound Gel (K020325); April 15, 2002

Device Description:

L.A.M. IPM Wound Gel is a clear viscous, odorless, aqueous gel composed principally of sodium hyaluronate, a derivative salt of Hyaluronic acid. L.A.M. IPM Wound Gel provides a moist wound environment that is supportive to wound healing. Over-the-counter use of L.A.M. IPM Wound Gel is suitable for minor burns, minor abrasions, and minor cuts. Under the supervision of a healthcare professional, L.A.M. IPM Wound Gel is suitable for exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), for the management of mechanically or surgically debrided wounds, and for second degree burns.

Intended Use:
Over The Counter:
L.A.M. IPM Wound Gel provides a moist wound environment that is supportive to wound healing. Over-the-counter use of L.A.M. IPM Wound Gel is suitable for minor burns, minor abrasions, and minor cuts.

Prescription (Rx):
Under the supervision of a healthcare professional, L.A.M. IPM Wound Gel is suitable for exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), for the management of mechanically or surgically debrided wounds, and for second degree burns.

Comparison with Predicate Device:

There have not been any changes to L.A.M IPM Wound Gel (K020325) since FDA determined that it was substantially equivalent to ConvaTec's HA Absorbent Wound Dressing (K984388) and Fidia Pharmaceutical Corporation's Bionect® Hydrogel (K984413) on April 15, 2002.

Trade Name	**L.A.M. IPM™ Wound Gel** (K020325)	**Bionect® Hydrogel (Jaloplast™)** (K984413)	**L.A.M. IPM™ Wound Gel** (Not Yet Assigned – modified indication)
Classification Name	Hydrogel Wound and Burn Dressing	Hydrogel Wound and Burn Dressing	Hydrogel Wound and Burn Dressing
Intended Use	Provides a moist wound environment that is supportive to wound healing	Provides a moist wound environment that is supportive to wound healing	Provides a moist wound environment that is supportive to wound healing
Indication for Use	Over-the-counter: • Minor abrasions • Minor cuts Under the care of a healthcare professional: • Wounds such as leg ulcers, pressure ulcers, and diabetic ulcers • Mechanically or surgically debrided wounds	Over-the-counter: • Minor burns • Superficial cuts • Lacerations and abrasions • Minor skin irritations Under the care of a healthcare professional: • Wounds such as partial to full thickness dermal ulcers (pressure ulcers, venous stasis ulcers, arterial ulcers, diabetic ulcers) • Surgical wounds (post-operative incisions and donor sites) • Second degree burns	Over-the-counter: • Minor burns • Minor abrasions • Minor cuts Rx: Under the care of a healthcare professional: • Wounds such as leg ulcers, pressure ulcers, and diabetic ulcers • Mechanically or surgically debrided wounds • Surgical wounds (post-operative incisions and donor sites) • Second degree burns

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Glycobiosciences, Incorporated
% Focal Point Research, Incorporated
Mr. Kevin Drizen
President
7 Timber Court
Gerogetown, Ontario L7G 4S4
Canada

February 8, 2013

Re: K123113
Trade/Device Name: L.A.M. IPM Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated (Date on orig SE ltr): September 25, 2012
Received (Date on orig SE ltr): October 03, 2012

Dear Mr. Drizen:

This letter corrects our substantially equivalent letter dated December 11, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, For

Peter D. Romm -S

Mark Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K123113

Indications for Use

510(k) Number (if known): K123113

Device Name: L.A.M. IPM Wound Gel

Indications For Use:

"OTC:
L.A.M. IPM Wound Gel is indicated for the management of minor burns (1st degree burns), minor abrasions and minor cuts.

Rx:
Under the supervision of a healthcare professional L.A.M. IPM Wound Gel is indicated for the management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and 2nd degree burns"

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123113